

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant(s): K. Bortlik et al.
Appl. No.: 10/057,660
Conf. No.: 4348
Filed: January 25, 2002
Title: PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE
COMPOUND
Art Unit: 1651
Examiner: R.A. David
Docket No.: 112701-593

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated August 21, 2007 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated August 3, 2006 as noted in Appellants' Appeal Brief filed on May 16, 2007 for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 65-76, 78-82 and 86-93 be reversed.

II. THE REJECTION OF CLAIMS 65-76, 78-82 AND 86-93 UNDER 35 U.S.C. §102(b) SHOULD BE REVERSED BECAUSE SCHMITZ FAILS TO DISCLOSE OR SUGGEST EVERY ELEMENT OF THE CLAIMED INVENTION

Appellants respectfully request that the Board reverse the anticipation rejections of Claims 65-76, 78-82 and 86-93 under 35 U.S.C. §102(b) because the Examiner has still failed to provide sufficient evidence that each and every limitation of the present claims is disclosed by *Schmitz*. In this regard, the Examiner has failed to properly interpret the claim language and specifically the claim element “mixture.”

a. The Examiner has not properly interpreted the present claim language.

Appellants respectfully disagree with the Examiner’s assertion that the term “mixture” as used in the present claims and described in the specification does not require a homogenous composition, or exclude encapsulation or core-containing compositions. See, Examiner’s Answer, page 6, lines 11-13. The Examiner alleges that the terms “mixture” and “homogenous” are not considered interchangeable in view of their customary meanings as defined by On-Line Medical Dictionary. The Examiner further states that “[i]t is noted that the specification fails to define the term “mixture,” thus the term is presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art,” according to the Manual of Patent Examining Procedure (MPEP) § 2111.01 III. Appellants respectfully disagree and submit that the Examiner has not properly interpreted the present claim language in accordance with the teachings of the Federal Circuit.

In part, the propriety of this rejection lies in the interpretation of the claim language “mixture.” To properly interpret claim language, the Federal Circuit has held that claims must be read in view of the specification, of which they are a part. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). Moreover, intrinsic evidence in the form of the patent specification should guide claim construction. Along these lines, the Federal Circuit recently reinforced the importance of the specification when interpreting claim language:

[t]he claims, of course, do not stand alone. Rather, they are part of "a fully integrated written instrument," *Markman*, 52 F.3d at 978,

consisting principally of a specification that concludes with the claims. For that reason, claims "must be read in view of the specification, of which they are a part." *Id.* at 979. As we stated in *Vitronics*, the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."

Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (emphasis added). Therefore, although the phrase "mixture" is not explicitly defined in the specification, the best source of information to determine what is meant by "mixture" is the specification, which must be taken into consideration when defining claim language. It is axiomatic that the Appellants' use of a term controls how that term is interpreted.

In contrast to the Examiner's assertion that the term "mixture" should be given its ordinary and customary meaning because it is not explicitly defined in the specification, the MPEP clearly states that "words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification." *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (emphasis added). Appellants respectfully submit that the term "mixture" as used in the specification is clearly meant to be interpreted as a homogenous mixture of LBC and whey protein, and not as just any combination of 2 or more substances as suggested by the Examiner.

For example, in the specification, several examples illustrate that the whey protein may be dissolved in a solvent. Similarly, the LBC may also be dissolved in another solvent. Upon dissolution of the whey protein and the LBC, the solutions are then mixed before the solvents are evaporated. See, specification, page 8, line 19-page 10, line 11; Example 1. Further, "solutions" are a type of a mixture commonly known to the skilled artisan. In fact, a "solution" is a homogeneous, molecular mixture of two or more substances. See, www.dictionary.com, definition of "solution" (emphasis added). Terminology such as "solution," "solvent," and "dispersion" are used repeatedly throughout the specification. Therefore, even though the term "mixture" is not explicitly defined in the specification, it is axiomatic that the Appellants' use of a term controls how that term is interpreted. As clearly indicated by the manner in which the term "mixture" is used in the specification, it is clear that Appellant's intended the term to comprise a homogenous mixture.

Although limitations in the specification cannot be incorporated into the claims, Appellants respectfully submit that the specification must be considered when determining how Appellants intended the term “mixture” to be interpreted. As such, Appellants respectfully submit that, in contrast to the Examiner’s assertion, the term “mixture” does, in fact, mean that the LBC and whey protein are combined into one homogenous solution.

In contrast, and as discussed in Appellants’ *Affidavit* filed November 22, 2006, *Schmitz* discloses a health food product containing a first component in the form of a discrete portion (*i.e.*, core) from a second component. Appellants respectfully submit that one having ordinary skill in the art would not use the term “mixture” when describing the relationship of a first the inner core and a second outer component of a product. Instead, they would be considered adjacent or discrete. A “mixture,” on the other hand, refers to a greater level of integration of two components rather than placing them next to each other.

Moreover, as discussed in Appellants’ *Affidavit*, Appellants have clearly demonstrated that the skilled artisan would understand the differences between the “mixture” of Appellants’ claimed invention and the discrete portions in the product of *Schmitz*. For example, the *Affidavit* clearly indicates the following:

Schmitz’s teaches protecting compounds from oxidation via internalization or containing within a lipid core. *Schmitz* specifies that the antioxidants are localized in a lipid-based carrier within the food product. *Schmitz* does not teach increasing the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins in accordance with the present invention. In contrast to the discrete, internalization form in a lipid-based carrier taught by *Schmitz*, the LBC is distributed uniformly throughout the whey protein in the present invention, thereby providing the unexpected and important benefit of increased bioavailability of the LBC. The compound of *Schmitz* would not result in increased bioavailability of the LBC because it is internalization in the lipid-based core. As a result, I believe that *Schmitz’s* product does not inherently achieve the same function as the claimed invention.

See, *Affidavit*, page 3, lines 6-17. Therefore, it is clear that the term “mixture,” as used by Appellants in the specification comprises a homogenous mixture, in contrast to the product of *Schmitz*, which teaches internalization of a lipid core that does not results in the increased bioavailability of LBC, as is required by the present claims.

It is only by disregarding the proper standards for claim interpretation that the Examiner can reject the claimed invention.

b. *Schmitz* fails to disclose or suggest other elements of the present claims

As Appellants have demonstrated above, and in previously filed correspondences, the phrase “mixture” should be interpreted to comprise a homogenous mixture. Appellants’ instant claims recite, in part, a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. In contrast, Applicants respectfully submit that *Schmitz* is deficient with respect to the present claims.

Appellants respectfully disagree with the Examiner’s assertion that “the composition of *Schmitz* must necessarily perform the functions as disclosed by appellants” because *Schmitz* teaches the claimed amounts of whey and LBC. See, Examiner’s Answer, page 7, lines 7-11. In contrast, Appellants respectfully submit that *Schmitz*’s product fails to achieve increasing the bioavailability of the LBC with whey protein in accordance with the present invention. As discussed above, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For example, rather than being in a lipid-based carrier as in *Schmitz*, the LBC of the present claims is distributed uniformly through a whey protein thereby providing the unexpected and important benefits of increased bioavailability of the LBC.

Because the compositions of the present invention, requiring a “mixture,” and *Schmitz*, having two discrete portions, are distinct, Appellants respectfully submit that the Examiner’s argument that “the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer” is rendered moot. Appellants respectfully submit that one skilled in the art would find that *Schmitz* entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by a whey protein matrix.

For at least the reasons discussed above, *Schmitz* fails to teach, suggest, or even disclose independent Claims 65 and 90, and Claims 66-76, 78-82 and 86-93 that depend from either

Claim 65 or Claim 90, and thus, fails to anticipate the present claims. Accordingly, Appellants respectfully request that the rejections of Claims 65-76, 78-82 and 86-93 be reversed.

III. CONCLUSION


For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the anticipation rejections with respect to Claims 65-76, 78-82 and 86-93.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-593 on the account statement.

Respectfully submitted,

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BY



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Dated: October 18, 2007